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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,060

03/15/2005

Wilhelm Scherze

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K.F. ROSS P.C.
5683 RIVERDALE AVENUE
SUITE 203 BOX 900
BRONX, NY 10471-0900

EXAMINER

WOOD, AMANDA P

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

05/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,060	Applicant(s) SCHERZE ET AL.	
	Examiner Amanda P. Wood	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-14 are pending and are presented for consideration on the merits.

Specification

The disclosure is objected to because of the following informalities: The preliminary amendment filed on 15 March 2005 "Cross Reference to Related Applications" appears to have an error. The amendment states that the PCT application number from which the instant application depends, PCT/EP2002/010357 claims priority to itself, PCT/EP2002/010357.

Appropriate correction is required.

Claim Objections

Claim 1 is objected to because of the following informalities: In claim 1, line 1, the word "A" should be inserted before the word "method." Appropriate correction is required.

Claim 1 is objected to because of the following informalities: The first "of" in steps a) through f) of claim 1 is grammatically incorrect. Appropriate correction is required.

Claims 2-14 are objected to because of the following informalities: In line 1 of each of claims 2-14, the word "The" should be inserted before the word "method." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, in claim 1, step f, Applicant recites the phrase "permanent measuring of all relevant cell culture parameters by means of suitable sensors integrated in the at least one cell culture chamber." It is unclear what constitutes "all relevant cell culture parameters" (e.g., it is unclear what parameter Applicant would consider relevant to measure).

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required

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feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "cultivating cells of the most diverse type," and the claim also recites "particularly human or animal cells" which is the narrower statement of the range/limitation.

Regarding claim 1, the phrase "or the like" in lines 5-6 renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Regarding claim 11, the phrase "i.e." renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 1 recites the limitation "the relevant culture" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the process" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "the starting" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the application" and "the method for indirect co-cultivation" in lines 2-3. There is insufficient antecedent basis for these limitations in the claim.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 11-14 rejected under 35 U.S.C. 102(b) as being anticipated by Kearney (US 5,424,209).

A method for cultivating cells in a defined environment is claimed.

Kearney teaches a method for culturing and testing of cells and tissues in a fully controlled thermal and gaseous environment, using an automated system (i.e., cell culture system) which provides a precision metering system for the introduction of controlled volumes of media as well as in-line detectors and monitoring devices allowing continuous assessment of the viability and metabolic state of each cell without the need for invasive procedures. Furthermore, Kearney teaches that the system includes a computer control allowing adjustment of rates of oxygenation, nutrient feed, and operation of heat control. Kearney also teaches that the system has a temperature sensor within each bioreactor (i.e., cell culture chamber) in the system which senses the temperature and conveys this information to the onboard computer control to provide

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accurate temperature control. Kearney teaches that a computer-controlled fluid pathway provides a supply of media, nutrients and chemical agents to the cells of the bioreactors, allowing control of administration of fluids as well as removal thereof. The bioreactors can be connected either in series or in parallel, according to Kearney (see, for example, col. 5, lines 55-67, col. 6, lines 1-10, col. 20, lines 30-50). Furthermore, Kearney teach that gases are continuously passed from bioreactor to bioreactor via a series of serially disposed T-unions (see, for example, col. 14, lines 45-67). In addition, Kearney teaches that the invention can include an automated microscope/CCD camera system to allow direct microscopic analysis of living cells during the study (see, for example, col. 20, lines 15-35). Kearney further teaches that determining the biotransformation of test materials can be accomplished by connecting two bioreactors in series, wherein the first bioreactor contains a target tissue and the second bioreactor contains hepatic tissue, and effluent from the second bioreactor may be removed for analytical testing, or cells may be observed directly (see, for example, col. 20, lines 30-67).

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney in view of Pfaller (US 6,329,195).

Kearney is relied upon for the reasons set forth above.

Kearney does not expressly teach a method wherein one cell culture, each of a different type, is established on both sides of a gas-permeable membrane inside at least one cell culture chamber for the purpose of a direct co-cultivation of both cell cultures.

Pfaller beneficially teaches a cell culture support and method for co-culturing cells wherein the inflow and outflow channels are designed to provide homogenous replacement of medium, thereby offering the possibility to perfuse nutrients of different composition at the top (apical) and bottom (basal or basolateral) side of the cell culture growth support. Pfaller further beneficially teaches that the cell culture growth support is bounded by a gas permeable membrane on both sides, and therefore, Pfaller teaches a method wherein different cell types are cultured on both sides of a gas permeable membrane in a cell culture chamber for direct co-cultivation.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method and system of culturing cells disclosed by Kearney based upon the beneficial teachings provided by Pfaller, with respect to the art-recognized method of co-culturing cells by providing two different nutrient compositions to apical and basolateral cells, as discussed above. Kearney specifically teaches that his automated cell culturing system can be used for co-culturing cells, and that co-cultures of rat myocytes and neuronal tissue have been grown and tested using the system. Pfaller specifically teaches a method and

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apparatus that has an advantage over other cell culture systems in that it provides means for continuous replacement of culture medium while allowing for defined partial pressures of gases in immediate contact with the culture medium due to the use of a membrane impermeable to liquids but permeable to gases. Furthermore, Pfaller teaches that such a system allows for the perfusion of different medium to the apical and basolateral sides of the cell culture support, thereby providing organotypic culture conditions. Therefore, it would have been both obvious and beneficial for one of ordinary skill in the art to modify the methods and systems provided by Kearney using the methods of Pfaller, so as to provide a method for direct co-culture of cells while still providing a self-contained environment free from contamination, for the expected benefit of culturing cells under conditions similar to that found in vivo.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Conclusion

No Claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

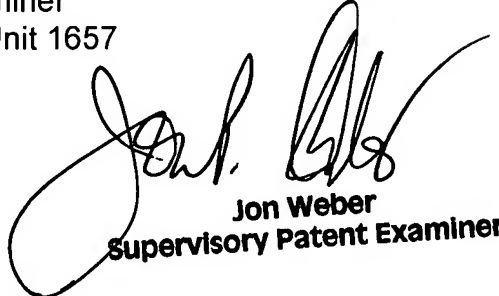
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW
Examiner
Art Unit 1657

APW



Jon Weber
Supervisory Patent Examiner